DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25, 2014

SpineFrontier, Incorporated
% Ms. Meredith May
Senior Manager
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K141333
Trade/Device Name: Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: October 14, 2014
Received: October 30, 2014

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director,
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)* K141333

Device Name
Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device

Indications for Use *(Describe)*

The SpineFrontier® Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc.

The SpineFrontier® Arena-C® Cervical IBFD is intended to be used with supplemental spinal fixation system(s) cleared for use in the cervical spine (example: Anterior Cervical Plate Fixation).

Degenerative Disc Disease is defined as discogenic pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(K) SUMMARY

Submitter's Name:	SpineFrontier
Submitter's Address:	500 Cummings Center, Suite 3500 Beverly, MA 01915
Submitter's Telephone:	978.232.3990 x116
Contact Person:	Meredith L. May MS, RAC Empirical Consulting LLC 719.337.7579
Date Summary was Prepared:	25-Nov-14
Trade or Proprietary Name:	Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Classification:	Class II per 21 CFR §888.3080 Device Classification
Product Code:	ODP
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The purposed of this submission is to add titanium coating to the existing Arena-C® product line. The Arena-C Cervical Intervertebral Body Fusion Device with Titanium Coating is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc. The system is comprised of devices made of Peek Optima® with titanium coating, with various heights to fit the anatomical needs of a wide variety of patients. The device has raised contours on the superior and inferior surfaces that will resist the device movement following implantation.

The implants are provided in two configurations: straight and lordotic (6°) implant sizes for both configurations are offered in three footprints (12x14mm, 12x15mm, 11x17mm) and heights from 5mm – 12mm, in 1mm increments.

The SpineFrontier Arena-C Cervical Intervertebral Body Fusion Device with Titanium Coating is intended to be used with supplemental spinal fixation system(s) cleared for use in the cervical spine (example: Anterior Cervical Plate Fixation).

Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Arena-C Cervical Intervertebral Body Fusion Device with Titanium Coating implants are supplied sterile, are single use, and are fabricated from PEEK-OPTIMA® LT1® with titanium coating and tantalum markers for radiographic visualization.

INDICATIONS FOR USE

The SpineFrontier® Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc.

The SpineFrontier® Arena-C® Cervical IBFD is intended to be used with supplemental spinal fixation system(s) cleared for use in the cervical spine (example: Anterior Cervical Plate Fixation).

Degenerative Disc Disease is defined as discogenic pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The indications for use for the Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device is similar to that of the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device is made from material that is identical to the previously cleared and predicate devices. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1 Primary Predicate

510k Number	Trade or Proprietary or Model Name	Manufacturer
K141337	Arena-C®™ Cervical IBFD	SpineFrontier

Table 5-1 Additional Predicates

510k Number	Trade or Proprietary or Model Name	Manufacturer
K090064	Interbody Fusion System	Eminent Spine
K130573	Interbody System	Tyber Medical

PERFORMANCE DATA

The Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device has been tested in the following test modes:

- Static Axial Compression per ASTM F2077
- Static Compression-Shear per ASTM F2077
- Static Torsion per ASTM F2077
- Dynamic Axial Compression per ASTM F2077
- Dynamic Compression-Shear per ASTM F2077
- Dynamic Torsion per ASTM F2077

Wear Particulate Analysis per ASTM F1877 on all dynamic test samples The Titanium coating has been evaluated with the following tests:

- Microstructure characterization per ASTM F1854
- Tensile testing per ASTM F1147
- Static shear testing per ASTM F1044
- Shear fatigue testing per ASTM F1160
- Abrasion per ASTM F1978

The results of this non-clinical testing show that the strength of the Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Arena-C® TiFuse™ Cervical Intervertebral Body Fusion Device is substantially equivalent to the predicate device.